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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/684,759
Filing Date: October 14, 2003
Appellant(s): WANG ET AL.

Reed Duthler
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 9, 2011 appealing from the Office action mailed September 10, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

80-82, 84-87 and 96-103

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being

maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,957,861	Combs et al.	9-1999
5,755,742	Schuelke et al.	5-1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. Claims 80-82, 84-87 and 96-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Combs et al. (US 5,957,861) in view of Schuelke et al. (US 5,755,742). Combs et al. discloses a system to produce impedance measurements in a subcutaneous portion of the body with at least two electrodes. "Also depending on the location of the electrodes used for measurement, it is wise to consider synchronization to the heart beat cycle and the respiratory cycles or the variation in measurement resulting from measuring at inconsistent times within these cycles may cause insurmountable difficulties in extracting useful signal from the impedance changes

created by these cycles. (col. 6, lines 51-57). Therefore, since the impedance measurements are synchronized with the cardiac cycle, they are responsive to a cardiac event.

"The determination of pulmonary edema or local edema will be based upon comparison of long term average impedance value compared to the short term average value" (col. 9, lines 64-67). "A determination of how severe the disease is by how quickly the edema progresses (i.e. if the change was seen over the course of two weeks, versus one day) becomes a measure that has value to the patient and physician and can be a stored value kept in a memory circuit by a device made in keeping with this invention"(col. 9, lines 53-59). Furthermore, "Long term average preferably represents the number of days (in the most preferred embodiment three to thirty) while the short term average represents the number of hours (preferably one to forty-eight)"(col. 10, lines 14-18).

Combs et al. discloses the claimed invention except for assessing the integrity of the leads. Schuelke et al. discloses a lead integrity measuring system that measured impedance values to determine lead integrity failures. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the system of Combs et al. to include a lead integrity measuring system as taught by Schuelke et al. in order to provide the predictable results of ensuring the leads are in proper working order. Furthermore, checking the integrity of the leads would ensuring the sensed values are accurate.

As to claims 86-87 and 102-103, Schuelke et al. discloses a device with three leads where each lead has an electrode. Wherein the third electrode provides a cross check of measured impedance values. "Testing current and voltage lead integrity of at least one of the leads comprising the steps of and means for: selecting one of the at least three leads as a lead under test, a force lead and a measure lead; coupling the terminal of the lead under test to a fixed potential; driving an excitation voltage pulse in an excitation path including the terminal of the selected force lead, the force lead electrode/tissue interface, the lead under test electrode/tissue interface and the lead under test; measuring the excitation current value of the excitation voltage pulse delivered in the excitation path through the lead under test; and measuring an induced voltage in a measure path including the terminal of the selected measure lead, the measure lead electrode/tissue interface, the lead under test electrode/tissue interface and the lead under test". The lead impedance of the lead under test is derived from the measured excitation current value and the induced voltage value. In order to test the lead integrity of the remaining leads, the selection of the lead under test, the force lead and the measure lead are changed, and the test is repeated"(col. 4, lines 46-65). Therefore, the modified Combs et al. discloses performing a cross-check of measured impedance values with a third electrode.

(10) Response to Argument

The Appellant contends that the "combined teaching suggests a device which measures both lead integrity and fluid content using impedance data obtained through two separate mechanisms".

This is incorrect. The combined teaching does not require two separate mechanisms for determining impedance as the Appellant contends. The combination teaches that it is known to sense impedance to determine intra-thoracic fluid content (Combs et al.) and to employ impedance data to assess lead integrity (Schuelke et al.). Therefore, it would have been obvious to take the already sensed impedance data from Combs et al. and further determine lead integrity as disclosed by Schuelke et al. The combination does not require additional mechanisms, and merely teaches the addition application for the already sensed impedance data.

In response to Appellant's argument that the two impedance sensing mechanisms can not be combined, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Additionally, the Appellant argues that the combined teachings do not execute impedance measurements with the same circuitry and are not measured at the same time. As previously stated, "the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references".

Furthermore, the combined teachings illustrate that it is known to utilize impedance data for determining intra-thoracic fluid content and that the sensed impedance data can also be used to assess lead integrity. Nothing prevents the impedance data sensed by Combs et al. to further be utilized in assessing lead integrity, especially since there is no additional physical structure for employing "the measured impedances to assess the integrity of the leads" recited in the claims.

The entire invention of the secondary reference need not be included in the combination. The combination merely teaches that it is known to use impedance data for: determining intra-thoracic fluid content AND assessing lead integrity.

In addition, the Appellant argues that the combined references do not disclose cross-checking of measured impedance values. However, as stated in Schuelke et al. at col. 4, lines 46-65, the lead integrity is assess by testing current and voltage lead integrity of at least one of the leads comprising the steps of and means for: selecting one of the at least three leads as a lead under test, a force lead and a measure lead. Since each lead has at least one electrode, the modified Combs et al. utilizes a third lead/electrode that is used to cross-check the lead integrity.

Lastly, the Appellant argues that the combined references do not declare the impedance data flawed in response to the assessed lead integrity. As previously made of record and stated above, "Furthermore, checking the integrity of the leads would ensuring the sensed values are accurate." When the integrity of the lead is compromised, the values sensed are necessarily considered to have been compromised as well. Therefore, determining the integrity would necessarily determine

if the impedance data is considered flawed as well. Therefore, the modified Combs et al. does disclose the determination of the measured impedances to be flawed in response to the assessment of the lead integrity.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/ALYSSA M ALTER/

Examiner, Art Unit 3762

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